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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,544	07/19/2001	Tom F. Lue	220022001600	1956

25225 7590 06/03/2003

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EXAMINER
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QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

17

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/909,544

Applicant(s)

LUE ET AL.

Examiner

Celine X Qian

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 23-27, 31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-27, 31 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1636

### **DETAILED ACTION**

Claims 23-27, 31 and 32 are pending in the application.

This Office Action is in response to the Amendment filed on 3/19/03.

#### ***Response to Amendment***

Acknowledgement is made of Applicants' submission of corrected drawing.

Acknowledgement is made of Applicants' submission of a Declaration under 37 CFR §1.132. It is noted, however, the declaration is not properly executed because it is not signed.

The rejection of claims 23-32 under 35 U.S.C. 112 1<sup>st</sup> paragraph (written description) has been withdrawn in light of Applicants' amendment of the claims.

The rejection of claims 23-32 under 35 U.S.C. 112 2<sup>nd</sup> paragraph has been withdrawn in light of Applicants' remarks and amendment of the claims.

The rejection of claims 23-27, 31 and 32 under 35 U.S.C. 112 1<sup>st</sup> paragraph (scope of enablement) is maintained for reason set forth of the record mailed on 12/18/02 and further discussed below.

The rejection of claims 23, 25, 27 and 31 under 35 U.S.C. 102 (a) is maintained for reason set forth of the record mailed on 12/18/02 and further discussed below.

#### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 112***

Claims 23-27, 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating male erectile dysfunction induced by cavernous nerve damage by administering BDNF to the patient, does not reasonably provide

Art Unit: 1636

enablement for a method of preventing or treating male erectile dysfunction because of other factors by administering BDNF. Further, the specification does not provide support for a method of preventing male erectile dysfunction induced by cavernous nerve damage by administering BDNF to the patient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

In response to the rejection, Applicants allege that the Examiner based the enablement rejection on personal knowledge or opinion and request support of the opinion by an affidavit. Applicants further argue that the claimed invention is enabled based on the experimental data submitted with the Lue 132 declaration.

The above argument has been fully considered but deemed unpersuasive. The reasons for the enablement rejection were discussed in detail in the Office Action mailed on 12/18/02. Applicants' allegation that the rejection is based on examiner's personal knowledge and opinion is not accurate. The quoted sentence "Given the complexity of the cause and molecular mechanism of male erectile dysfunction..." is based on the teaching of the prior art rather than personal experience. The prior art, for example, Maytom (6,436,944), teaches "impotence can result from psychological disturbance, physiologic abnormalities or a combination from both. Thus, in some males...erectile dysfunction is associated with atherosclerosis of the arteries supplying blood to penis...venous leakage from veins in penis...typically, multiple factors are responsible for impotence (see col.1, lines 26-42)." Based on the teaching of the prior art, it is logical to conclude that targeting one factor of the ED is not going to be effective against ED

Art Unit: 1636

caused by other factors. Such statements are not based on the Examiner's personal knowledge, therefore, an affidavit is not required.

The Declaration under 37 CFR 1.132 filed on 3/19/03 is not properly executed because the inventor fails to sign the Declaration. The experimental data provided by the Declaration is not considered because the Declaration is defective.

Based on the teaching of the specification, the claimed invention is only enabled for the scope of a method of treating male erectile dysfunction induced by cavernous nerve damage by administering BDNF to the patient.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 23, 25, 27 and 31 are rejected under 35 U.S.C. 102(a) as being anticipated by Bakircioglu et al.

Applicants submitted the Lue 132 Declaration to overcome this rejection. However, since the Declaration is defective (unsigned), this rejection is maintained for same reason set forth of record in the office action mailed on 12/18/02. This rejection will be removed once Applicants provide a properly executed Declaration under 37 CFR 1.132.

***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

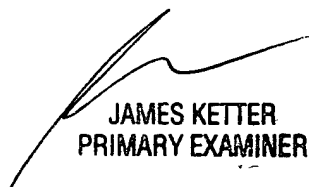
Application/Control Number: 09/909,544

Page 6

Art Unit: 1636

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.  
June 2, 2003



JAMES KETTER  
PRIMARY EXAMINER